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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,370	12/21/2001	Jeffrey A. Trogolo	A-036	5277

7590 02/08/2007

AGION TECHNOLOGIES
60 Audubon Road
Wakefield, MA 01880

EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/032,370	TROGOLO ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-22,33,34,45,48-51 and 53-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-22,33,34,45,48-51 and 53-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Information Disclosure Statement and Applicant's remarks dated 11/10/06 is herein acknowledged.

Status of Claims

Claims *1-7,10-22,33,34,45,48-51 and 53-63 are* pending in the application.

Status of Office Action: Final.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 10-12, 22, 33, 34, 48, and 49 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hagiwara et al. US 4775585 (Hagiwara).

Hagiwara teaches a polymer article having antibacterial properties as well as a physical property similar to those of the polymer itself, which contains zeolite particles retaining metal-ions, which show an antibacterial effect at the ion-exchange sites of the zeolite particles. The zeolite particles are retaining one or more metal ions having a bactericidal property (col. lines 56-59). The polymer can be highly hydrophilic (col. 8, lines 7+) and the antimicrobial can be a metal salt of a metal having a bactericidal activity, such as silver, copper and zinc (col. 3, lines 12+). A particle size of the zeolite can suitably be selected depending on application fields. When granules or coarse fibers, the particle size may be in the range of a few microns to tens microns or even above several hundred microns (col. 4, lines 9+). Note that a fiber is inherently a high

aspect ratio particle and that the ratio recited in instant claim 1 as greater than about 2 is also inherent in fibers because the fiber's length is usually -if not mostly- more than double its width or diameter. Note that the definition of fiber is as follows.

Fiber:

Materials: A thin, threadlike piece of any material.

"fiber". Academic Press Dictionary of Science and Technology (1992). Retrieved 28 August 2006, from xreferplus. http://www.xreferplus.com/entry/3104363.

The fibers or the yarns according to Hagiwara can be mix woven, cross woven or union knitted with fibers or yarns having no metal-zeolite to give an antibacterial fiber article with various feelings and functions. This limitation reads on the limitations of instant claims 33, and 34.

Note also that, because Hagiwara uses polyurethane in an antimicrobial composition, it is inherently having water absorption at equilibrium of at least about 20% by weight.

Accordingly, claims 1-4, 10-12, 22, 33, 34, 48, and 49 are anticipated by Hagiwara.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,10-22,33,34,45 and 48-51, 53-63 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hagiwara et al. US 4775585 (Hagiwara) in view of Trogolo et al. US 6436422 (Trogolo), Gibson et al US 6413536 (Gibson) and further in view of Michal et al. US 6287285 (Michal).

Hagiwara has been discussed above.

Hagiwara is deficient in disclosing the ceramic type of carrier, the ratio of hydrophilic polymer, the inorganic discoloration inhibiting agent; and the sodium nitrate dopant.

Trogolo discloses an antibiotic coated substrate having an antibiotic coating composition coated thereon. The coating composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite dispersed therein. The antibiotic zeolite may further comprise a discoloration agent (abstract). Antibiotic ceramic particles include zeolites, hydroxyapatite, zirconium phosphates and other ion-exchange ceramics. Any suitable hydrophilic polymer may be employed, including hydrophilic polyurethane. Trogolo used in the preferred antibiotic zeolite preferred embodiment, ion-exchangeable ions present in zeolite, such as sodium ions, calcium ions, potassium ions and iron ions are partially replaced with ammonium and antibiotic metal ions. Such ions may co-exist in the antibiotic zeolite particle since they do not

prevent the bactericidal effect. Examples of antibiotic metal ions include, ions of silver, copper, zinc, mercury tin, lead, bismuth, cadmium, chromium and thallium. Preferably, the antibiotic metal ions are silver, copper, or zinc ions, and most preferably silver is employed. These antibiotic metal ions may be incorporated into the zeolite by themselves or in a mixture (col. 3 lines 21-65.) A discoloration agent may be added to the antibiotic hydrophilic polymer. The inorganic discoloration inhibitor is an ion-exchanged ammonium ion in the antibiotic zeolite. The substrate may be any substrate to which the hydrophilic polymer adheres, including glass, plastic, metal, and woven and non-woven fabrics. An article comprising a substrate on which is coated with the antibiotic hydrophilic coating may also be used. The article may be a medical article, such as a catheter, stent, heart valve, or paper (col. 5 lines 22-55.) The solids in the coating solution preferably contain from about 0.01 to about 90% by weight of antibiotic zeolite and from about 10% to about 99.99% by weight of hydrophilic polymer. Trogolo discloses a method of altering the release of the antimicrobial because as disclosed in the reference, in medical device embodiments, the coating preferably exhibits a release rate ranging from about 5 to about 50 ppb of microbiocidally effective silver ions upon contact of the medical device with body tissues or when contaminated outside of the body with, e.g., microbes transferred from uncovered hands, for a period of more than 1 week (col. 3, lines 43+). However Trogolo does not disclose immersing the particles in a different polymer to alter the release.

Gibson discloses a general teaching of category of biodegradable polymer additives to pharmaceutical compositions. The polymers can be used to alter the

release profile of the substance to be delivered, to add integrity to the composition, or to otherwise modify the properties of the composition (col. 15, lines 47+). Also another additive for use with compositions are non-biodegradable polymers. Non-limiting examples of nonerodible polymers which can be used as additives include polyurethanes (col. 16, lines 4+).

It would have been obvious to one of ordinary skills in the art to use the teaching of Gibson by adding the high aspect ratio particles of both Hagiwara and Trogolo into a polymer to alter the release of the particles.

Hagiwara and Trogolo as disclosed above are silent regarding a dopant, specifically sodium nitrate.

Michal discloses a method of providing a therapeutic, diagnostic or lubricious hydrophilic coating on and intra-corporeal medical device (abstract). Additionally, nitric oxide donor drugs may be used as a vasodilator relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. A variety of suitable nitric-oxide donor drugs include sodium nitrate (col. 4).

Absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Trogolo by adding a dopant specifically sodium nitrate as taught by Michal because of the expectation of relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. Both Trogolo and Michal teach medical devices, specifically medical devices coated with a hydrophilic polymer. Therefore, it would have been obvious to add sodium nitrate to the composition of Kagiwara for the added benefits taught by Michal. The

expected result would be a high aspect ratio antimicrobial composition comprising a hydrophilic polymer, an antimicrobial agent and a discoloring agent and a dopant.

Response to Arguments

Applicant's arguments filed 11/10/2006 have been fully considered but they are not persuasive.

Anticipation in view of Hagiwara et al. US 4,775,585.

Applicant argues that:

1. Nowhere in Hagiwara is there any suggestion of microparticles of the polymer having dispersed therein even smaller particles of the antimicrobial agent or any reference to "molded particles" in the micron size range. In the examples, Hagiwara speaks of spinning fibers or forming staples from which the fibers are spun; both of which, as noted, would be expected to have aspect ratios above 2; however, the fibers are identified as long continuous filaments/yarns and the staples, from which the latter may be spun, have a length of 51mm. And while Hagiwara discloses that the antimicrobial fibers may be combined with non-antimicrobial fibers this is completely different from and non-enabling of a polymer composition comprising therein discrete particles of a second polymer, the latter having dispersed therein an antimicrobial agent. Further, but for the one reference to the use of "a relatively highly hydrophilic polymer". No other mention is made of hydrophilic materials, nor is any mention made whatsoever to water absorption at equilibrium of any polymer.

To respond to this argument: instant claim 1 does not recite any microparticle polymer, it only describes "an antimicrobial additive being in the form of a microparticle".

Note that the antimicrobial in instant claim 1 is the inorganic particles while the polymer is not recited as being in a microparticle form. The instant claims also do not recite any molded particles as argued by Applicant. Hagiwara does not only teach spinning fibers but Hagiwara also discloses, "When fibers or films are molded as an article according to the present invention, preference is given to a smaller size of particle. For instance, the particle size of 5 microns or less, especially 2 microns or less is preferred for fibers to be used in clothes." Col. 4, lines 9+. With regard to Applicant contention that Hagiwara's reference is non-enabling of a polymer composition comprising therein discrete particles of a second polymer. Again instant claim 1 does not recite a "polymer composition", it only recites an antimicrobial agent in particle form, one or more antimicrobial metals and a hydrophilic polymer comprised in the "antimicrobial additive composition" not the "polymer composition". It is also noted that the polymer is not recited in the instant claims as "a relatively highly hydrophilic polymer", however, Hagiwara suggested the use of polyurethane which is the same hydrophilic polymer recited in the instant claims. Consequently, it is not necessary that the reference describes literally what the instant claims recite since it is using the same polymer; it would inherently have the same characteristics.

2. Applicant argues that: nowhere does Hagiwara suggest or teach the formation of high aspect ratio, microparticles of the use thereof as an additive for polymer matrix resins. As noted above, the smallest molded article shown or described by Hagiwara is the 51mm fiber staples, the smallest article altogether is the 20mm discs cut from the molded article for purposes of evaluating bactericidal activity (the latter, however, have

a 1:1 aspect ratio). On the other hand, as noted, the largest dimension allowed by Applicants microparticles is 500 microns, a mere 1/100th that of the staple and 1/40th that of the cut disc of Hagiwara.

To respond: the intended use of the claimed composition has not been given patentable weight, because the prior art compositions would be at least capable of performing said use. Regarding the size of articles disclosed Hagiwara which Applicant contends that it is 100 times the recited particles, Hagiwara discloses that "When fibers or films are molded as an article according to the present invention, preference is given to a smaller size of particle. For instance, the particle size of 5 microns or less, especially 2 microns or less is preferred for fibers to be used in clothes." Col. 4, lines 9+.

Obviousness in over Hagiwara et. al. (US 4,775,585 - "Hagiwara') in view of Trogolo et. al. (US 6,436,422 - "Trogolo'), Gibson et. al. (US 6,413,536 - "Gibson") and further in view of Michal et. al. (US 6,287,28.5 "Michal')

Applicant contends that:

1. Nothing in Hagiwara teaches, suggests or infers microparticles of its compositions, let alone of an antimicrobial hydrophilic composition, nor is it even clear how one might "mold" such microparticles. Furthermore, there is no teaching, inference, or suggestion that such microparticles, if formed, could be used as and in substitution for the antimicrobial agents described therein. As set forth in great detail in Applicants last response, these microparticle additives are used as the antimicrobial agent for incorporation, into polymer compositions, like those of Hagjwara, for providing

enhanced ant/microbial performance as compared to the neat antimicrobial active agent itself.

To respond: As noted in the rejection above Hagiwara admixing zeolite particles previously provided with the metal ion with a polymer or by molding a zeolite-containing polymer into an article. In addition, the intent of use is not of patentable weight.

2. Despite the Examiner's assertion that "because Hagiwara uses polyurethane in an antimicrobial composition, it is inherently having a water absorption at equilibrium of at least 20% by weight" Hagiwara never exemplifies a polyurethane and, further, makes no mention of the degree of hydrophilicity. Indeed, the only reference to hydrophilic properties in all of Hagiwara is the one ancillary comment as to the antimicrobial performance when used in a "relatively highly hydrophilic polymer," As set forth in MPEP 2144.03(A), "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-know, or to be common knowledge in the art, are capable of instant and unquestionable demonstration as being well-known." The assertion that Hagiwara uses a hydrophilic polyurethane, let alone one having water absorption at equilibrium of at least 20 weight percent, is completely false and without foundation or support.

To respond: the reference disclosed polyurethane and indicated the hydrophilicity of the polymer and its effect on the invention. Note that Hagiwara's disclosure is not limited to the examples only, the reference is considered for its entirety.

3. Applicant argues that: Using the Examiner's reasoning, in hindsight, Hagiwara could also make a coated article as taught by Trogolo, yet it is clear that Trogolo was

patentable over Hagiwara as it was cited in the examination of Trogolo. Furthermore, Hagiwara could make any number of articles that are the subject of dozens, if not hundreds, of patents following Hagiwara; yet, again, these too were deemed patentable. Again, clearly, it is not a matter of "could" but what it taught or motivated.

To respond: Each application is treated on its own merits; the patentability of Trogolo and many others over Hagiwara does not provide and evidence of the patentability of the instant application over Hagiwara.

4. Applicant argues that: Further reliance upon Trogolo does not help establish prima facie obviousness. First, Hagiwara is directed to antimicrobial molded articles whereas Trogolo is directed to antimicrobial coating compositions for treating and, hence, imparting antimicrobial properties to articles and substrates. The former involves incorporating the antimicrobial agent into a polymer melt. The latter involves dissolving the polymer in a suitable solvent that has suspended therein the antimicrobial agent or combining two solutions, one having the dissolved polymer and the other having the suspended antimicrobial agent, and using the resultant solutions as a coating material, which, upon evaporation of the solvent, leaves an antimicrobial hydrophilic polymer film on the treated article or substrate.

To respond: Trogolo discloses an antibiotic coated substrate having an antibiotic coating composition coated thereon. The coating composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite, dispersed therein (see abstract). Hagiwara teaches polymer article having an antibacterial property containing zeolite particles therein wherein the composition can be used as a

coating material (col. 9, lines 55+). Note that the substrate of Trogolo is exemplified as a catheter, catheters are known to be made of polymers which shows that the disclosures Trogolo would not change the principal of operation of Hagiwara as contended by applicant.

5. Applicant argues that: nowhere does Trogolo speak of particles of a hydrophilic polymer with the antimicrobial zeolite and, as noted above, Hagiwara only suggests, as one of many shapes, granules. Nothing suggests i) microparticles as claimed, especially ones having an aspect ratio of greater than 2 and a maximum dimension of 500 microns and ii) the use of a hydrophilic polymer having a water absorption at equilibrium of at least 5 weight percent. Nor is there any motivation in either reference or the combined teachings, to prepare such microparticles. Since Trogolo prepares coatings, they only teach liquid materials that upon evaporation of the solvent, form polymer films on a substrate, not particles. Even if one could mold a 500 micron particle, there is no motivation to do so.

To respond: Trogolo is introduced into the rejection as a secondary reference for the disclosure of ceramic type of carrier, and the inorganic discoloration inhibiting agent. In addition, the microparticles size disclosed by Hagiwara is within the range recited in the instant application, reaching the upper limit of 500 microns is not required to prove anticipation or obviousness.

6. Applicant argues that: the teaching of Trogolo with respect to the compositional make-up of the coatings as well as the release rate of the antimicrobial active; however, again, this is relative to a coating: a homogeneous film of the antimicrobial polymer, not

particles, and certainly not microparticles. Furthermore, while Trogolo may suggest that the individual particles may release, there in no teaching or expectation of how that release may be effected when the individual particles are subsequently incorporated into another polymer. As noted elsewhere, the high aspect ratio antimicrobial additives of the present invention are useful as and are intended for use as substitutes for the neat antimicrobial agent of Trogolo and Hagiwara. Neither reference teaches, suggests, infers the option or desirability of using the antimicrobial hydrophilic polymer micro particles of the present invention in substitution for the neat organic antimicrobial agents used in each, let alone provides any expectation or prediction that such use will result in polymers, molded articles and coatings having enhanced antimicrobial performance, especially improved longevity and release control, regardless of the polymer into which they are added.

To respond: Applicant contends that Trogolo is related to a homogeneous film of antimicrobial and not to microparticles, the reference Trogolo US 6436422 does not disclose the word "homogeneous" even once, while the word film is disclosed once in the background of the invention as "Polymers incorporating antibiotic zeolites have been used to make refrigerators, dish washers, rice cookers, plastic film, chopping boards, vacuum bottles, plastic pails, and garbage containers " (see col. 1, lines 33+.). on the other hand Trogolo discloses a composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite, dispersed in the coating. The definition of the word partilcle is:

par.ti.cle
noun

1. A very small piece or part.

2. An elementary particle.

3. A subatomic particle.

APA | MLA | Chicago : **Citing this entry**
particle. (2002). In *The American Heritage Stedman's Medical Dictionary*. Retrieved February 04, 2007, from http://www.xreferplus.com/entry/2790247

While the definition of the prefix micro is:

micro-

Prefix meaning small, as in microcephaly (small head) and microsomia (small body). The opposite of micro- is macro-.

APA | MLA | Chicago : **Citing this entry**
micro-. (2003). In *Webster's New World™ Medical Dictionary*. Retrieved February 04, 2007, from http://www.xreferplus.com/entry/2437623

Accordingly, if Trogolo discloses a composition formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite dispersed therein and the antibiotic ceramic particles include zeolites, hydroxyapatite, zirconium phosphates and other ion-exchange ceramics, It is clear that Trogolo combined with Hagiwara are meet

the same limitations recited in the instant claims especially the microparticles (small particles). (see instant claims 1-7).

Regarding the release, Trogolo discloses that:

"An amount of antibiotic ceramic is dispersed in the hydrophilic polymer that is effective to release the antibiotic metal ions in a microbiocidally effective amount. In medical device embodiments of the present invention, the coating preferably exhibits a release rate ranging from about 5 to about 50 ppb of microbiocidally effective silver ions upon contact of the medical device with body tissues or when contaminated outside of the body with, e.g., microbes transferred from uncovered hands, for a period of more than 1 week." Contrary to the Applicant contention, Trogolo is clear with regard to how that release may be affected when the individual particles are subsequently incorporated into the polymer. In addition, people skilled in the art have been altering the release of different compositions for years though the use of different polymers. It is within the skills of an artisan to decide which polymer and in which shape (coat, matrix, ..etc) can the polymer be added to alter the release of any composition.

7. Applicant argues that:

First, it is believed that Gibson is truly non-analogous art. As set forth in MPEP 2141.01(a), " in order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the filed of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem, with which the inventor was concerned." Such a finding is not present here. Gibson is concerned with liquid, high viscosity materials suitable as carrier and delivery means for bio-active substances.

These materials are applied either as a topical paste, salve, or the like or as an implant or injected material to a living organism, e.g., a patient, animal, plant, etc., to effect delivery by release of a therein contained bio-active agent to the treated tissue. These nonpolymeric liquids may also contain minor amounts of certain polymer materials; yet, the compositions of Gibson are nevertheless liquid, non, polymeric, non- solidifying treatments. Such materials are of interest to doctors, veterinarians, horticultumlists, etc., but certainly of no interest or import to a molding or coating specialist. Furthermore, as noted, Gibson adds its bioactive agent to a Liquid, and specifically requires a liquid; whereas Applicant's add their antimicrobial agent to a solid and requires a solid. Gibson is directed to treatment of a living organism whereas Applicants are focused on preventing the growth of microorganisms on a substrate or article. Thus, not only are the fields of endeavor unrelated, but the very objectives are as well.

To respond: Gibson is relied upon for a general teaching of category of biodegradable polymer additives to pharmaceutical compositions. The polymers can be used to alter the release profile of the substance to be delivered, to add integrity to the composition, or to otherwise modify the properties of the composition (col. 15, lines 47+). Also another additive for use with compositions are non-biodegradable polymers. Non-limiting examples of nonerodible polymers which can be used as additives include polyurethanes (col. 16, lines 4+). Gibson's reference teaches that "the formulations containing biologically active substances and an HVLCM or LVLCM may be further formulated with polymeric excipients to provide a drug delivery matrix with modified properties, for example a faster or slower degradation rate (altered release). The

resulting composition may be formed into microspheres, or into a macroscopic implant, or other geometries and sizes according to techniques known in the art." Gibson also discloses that the composition may comprise antibiotic drugs and defines the term drug as it refers to any substance used internally or externally as a medicine for the treatment, cure, or prevention of a disease or disorder. It is additionally noted that the term antibiotic is equivalent to antibacterial and antimicrobial (col. 12, lines 14+). Accordingly, the reference is related to the same field.

8. Applicant argues that:

As noted above, Gibson teaches the combination of the liquid carrier and, dispersed therein, a bioactive agent and a polymer additive and tells us that the addition of the polymer additive affects the properties and characteristics of the liquid in several ways, one of which relates to the release of the bioactive agent. Both Hagiwara and Trogolo teach adding a solid antimicrobial agent to a solid polymer (or to the solution, of the polymer in the case of the uncured coating to impart antimicrobial characteristics to the solid polymer.

To respond: Gibson invention is related to biological active substance dispersed in the non-water soluble, high viscosity, liquid carrier material. The instant claims and Trogolo's disclosure are related to an antimicrobial (active material) dispersed in a solution of the polymer regardless of the intent of use as a coating, an additive or as a delivery system of active ingredients.

9. Applicant argues that: Trogolo teaches one to expect antimicrobial efficacy by coating a medical device with a hydrophilic polymer having incorporated therein an

antimicrobial agent Michal teaches that one can improve the ease with which a medical, device is inserted into a vessel or tissue by using a medical device that has been coated with a coating having a hydrophilic additive. Independently, it also teaches that one may use certain therapeutic agents, including nitric oxide donors, such as sodium ntitrate, as a coating additive to act as a vasodilator coatings to be applied to medical devices, such as stents, catheters and the like, to relax the smooth muscles of a vessel, again to aid in the insertion of the device. However, even if one beat the odds and came to that specific combination, there is nothing that would suggest that by doing so, in the unique circumstance that the coating also contained an ion-exchange type antimicrobial agent, the sodium nitrate would also serve as a dopant for the antimicrobial agent. Furthermore, there is nothing to suggest what effect, if any, the 'inherent' secondary role would have on the primary role, as a vasodilator, of the sodium nitrate.

To respond: The motivation of using the muscle relaxation agent (sodium nitrate) recited in the instant claims as dopant to the teaching of Michal to Higawara and Trogolo is clear because the skilled artisan would be motivated to add the muscle relaxation agent (dopant) for being useful in relaxing the muscles during the insertion of the substrates that have an antimicrobial effect such as catheters.

Note that the instant application is a composition that can be used in catheters (see instant specification) which discloses:

> [0062] The antimicrobial polymer and polymer coating compositions made in accordance with the practice of the present invention may be used in any applications where antimicrobial properties are desirable. Exemplary applications

include cutting boards, catheters and other medical devices, pipes, containers, toothbrushes, diapers, air filters, appliances, conveying belts, bottles, liquid dispensers, faucets, humidifiers, air conditioners, mats, razors, and bandages.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
2/4/2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER